



DEPARTMENT OF HEALTH & HUMAN SERVICES

35138d
Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

December 21, 2004

WARNING LETTER
2005-DT- 07

Mr. Douglas C. Klimesh
President
N64 Neutraceutica
2922 Roundtree Blvd.
Ypsilanti, MI 48197

Dear Mr. Klimesh:

The U.S. Food and Drug Administration (FDA or the agency) conducted an inspection of your firm, N64 Neutraceutica on September 22 and October 4, 7, and 18, 2004. During this inspection, you provided FDA's investigators with labeling for your firm's products, which the agency has reviewed. FDA has also reviewed your web site at the Internet address <http://www.grazoph.com>. Based on our review, we have determined that your products "Grazoph Temuna," "Grazoph Tipremunak," "WOWPOA," "Deparalysis Neutraceutical," "Curandaro's general herbal formulas," and "Personal Spectral Formulas" are promoted for conditions that cause them to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)(1)]. The therapeutic claims in your products' labeling, including your web site, establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

Products and therapeutic claims include, but are not limited, to the following:

Grazoph Temuna:

"About enough to clear one full blown Alzheimer's case." "What Grazoph Temuna is good for:"

- "Alzheimer's effects"
- "Preventative: Helps prevent many forms of dementias from taking hold. This is relief for the certain Alzheimer's Dementia diseases.... [M]ay be very helpful for preventing Pick's Disease and Creutzfeldt-Jakob Disease, and to a lesser extent Multi-Infarct Dementia. Is thought to work also to relieve azotemia, bactremia [sic], cellulitis, sinsusitis [sic]...."

"[T]reats that which is often called "detached retina" of eye"

"[S]aves victims of Mad Cow Disease (Creutzfeld-Jakob Disease) if applied in time."

Grazoph Tipremunak:

"[R]everse condition of Parkinson's disease...."

"Parkinson's Reverser-For Parkinson's Disease Only"

"Result of taking Grazoph Tipremunak: The general result of Parkinson's sufferers taking one packet of Parkinson's Reverser is that it clears tremors completely for several days, and reduces the depth of the disease typically by 5% overall. Additional treatment will continue to reduce the disease. Grazoph tipremunak may need to be used 12 times before Parkinson's is entirely eliminated."

WOWPOA:

"Guaranteed to eliminate migraines for six years."

"I had severe migraines for 30 years, then I met Jauncey. He gave me enough WOWPOA to neutralize my entire migraine." (Testimonial)

"Cerebrospinal Poison Antidote" (Product label)

"[T]he migraine dissolver" (Product label)

Deparalysis Neutraceutical:

"[H]elps serious self-healers overcome Spinal Paralysis."

Curandaro's general herbal formulas:

"Get rid of Cancer using the Curandaro's general herbal formulas. Guaranteed to eliminate cancer in one year and free from cancer for at least 5 years!"

Personal Spectral Formulas:

"[M]ultiple formulas totaling more than a hundred herbs and possibility of cancer and other diseases may be eliminated in the first days of the use of these personal spectral formulas."

"[S]pectral-formula-for-one-only also arrests pre-cancers, cancers which will not happen because of herbal medicines"

"Our Curanderos have developed formulas for Lung Cancer, Nose & Ovarian Cancers, Spinal Paralysis, Tuberculosis, Asthma, Diabetes, Gout. Our curandero has abilities and has accumulated [a] vast herb assortment useful for helping many type[s] of neural/mental conditions such as Grand Mal Seizures, Schizophrenia, Dementias, ... Traumatic Injury, ... Diabetes, Sarcoma, Schizophrenia, ... Parkinson's, Broken neck, Alcoholism [sic], ... Tuberculosis, Lupus, Asthma, Prostate Cancer We have a formula that permanently [sic] stops pain from Multiple Sclerosis"

Brain & Body Cleanser Power Pack:

"Helps prevent most kinds of Alzheimer's diseases" (Product label)

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21USC 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 USC 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. These drugs are also misbranded within the meaning of section 502(f)(1) of the Act [21 USC 352(f)(1)], in that the labeling for these drugs fails to bear adequate directions for use.

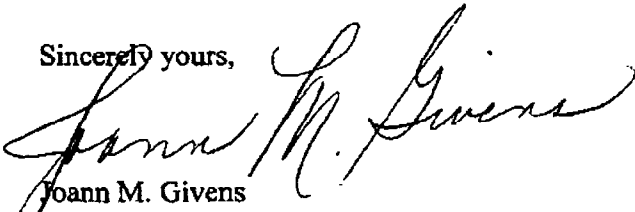
The above violations are not meant to be an all-inclusive list of deficiencies for your products or their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Mrs. Judith A. Putz, Compliance Officer, 300 River Place, Suite 5900, Detroit, MI 48207.

Sincerely yours,



Joann M. Givens
District Director

CC: Mr. Daniel Lexington
N64 Neutraceutica
2922 Roundtree Blvd.
Ypsilanti, MI 48197